

EXHIBIT 147

From: John Schultz
Sent: Thursday, September 4, 2008 4:00 PM
To: Mike Reiney; Charles V. (Trey) Propst; Spike Pannell; Jeremy Tatum
Subject: Qualitest 08-2008.doc
Attachments: Qualitest 08-2008.doc

All,

Attached is Mike's audit report from his visit. We will need to formulate a response and implement the corrective actions. Please provide comment on the observations with suggested corrective actions.

Thanks,

John

Review of
Qualitest Pharmaceuticals
130 Vintage Drive
Huntsville, AL 35811
August 19 – 20, 2008

Synopsis:

On August 19, 2008, Michael Mapes met with John Schultz, Spike Pannell, and Jeremy Tatum of Qualitest Pharmaceuticals at the Huntsville, AL facility. The purpose of the visit was to review the controlled substance order monitoring process that has been implemented to insure that Qualitest is not selling controlled substance for other than legitimate medical purposes. Files to document customer establishment were reviewed along with files from account representatives that documented the business being conducted by the pharmacies. The current Qualitest Standard Operating Procedures were reviewed. The newly created Controlled Substance Questionnaire was also reviewed.

The issues that were noted during the review were:

1. Reporting of Suspicious Orders to DEA, in addition to reporting Suspicious Sales.
2. Selling quantities of controlled substances that are under the Qualitest thresholds to pharmacies that have reached the thresholds with other distributors.
3. Establishing a "Pain Management Policy" similar to the "Internet Policy."
4. Maintenance of new Controlled Substance Questionnaire in the computer system.
5. Using sites such as www.legitscript.com to further review background on customers.

Details:

The Qualitest Pharmaceuticals SOP for Suspicious Orders was revised and effective as of 6-19-2007. The SOP states that Qualitest Senior Management will make a determination if a suspicious order is reported to DEA. A check with Mr. Schultz showed that in the past eight months no reports of suspicious orders were sent to DEA. While discussing issues with Jeremy Tatum, he was not aware that in addition to notifying DEA of sales that were above established thresholds and suspicious, they are expected to report to DEA suspicious orders, even if the sale was declined by Qualitest. The Qualitest system for reporting suspicious orders to DEA needs to be improved to comply with 21CFR1301.74.

In several instances, sales were made to a pharmacy that was under the established threshold for that drug established by Qualitest when the account representative was aware that the customer had been limited in quantity for the same drug by another wholesaler. Although this issue was discussed, no determination was made as to if Qualitest would continue to ship controlled substances in such cases.

Generally speaking, Jeremy Tatum is responsible for releasing orders for retail pharmacies and doctors where the quantity shipped is above the established thresholds for the particular drug as established by Qualitest. At the present time, the only information that Mr. Tatum has to consider when making the decision is the customer history, possible a note or email from the account representative, or input from the phone sales representative. It is imperative that the Controlled Substance Questionnaire that has been developed be finalized and put into the system. Without that level of information, Qualitest will be making the ship/not ship decision with insufficient information. Most other controlled substance distributors are using a similar questionnaire for background information on the pharmacies and doctors to whom they sell controlled substances.

When DEA started meeting with distributors to discuss the internet issue, Qualitest developed an affidavit that they sent to pharmacy customers to document that the pharmacy was not selling over the internet. The DEA emphasis on the distribution of specific drugs such as Hydrocodone products has now moved from the internet to pain management practices that use large quantities of Hydrocodone or other controlled substances. Qualitest should create a policy, similar to the internet SOP, to make all employees and customers aware of the pain management issue. The core issue is to assure that the drugs are prescribed and dispensed to a patient who has a legitimate relationship with the doctor.

Documentation in the file of information from account representative Walt Busbee related to Diversified Health Systems (DHS) documented that DHS is purchasing Qualitest products in large quantities and repackaging the products in unit of use sized and distribute the drugs to physicians. It is very important for Qualitest to work with DHS to assure that DHS has a system to be sure that their physician customers are only dispensing the drugs to patients for legitimate medical purposes.

It is important for Qualitest to work with all controlled substance customers, including those who will further distribute Qualitest products to other DEA registrants, to assure that the controlled substances are distributed only to customers who have systems in place to assure that the controlled substances will be used for legitimate medical purposes.